

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

VICKI WETZEL,)	CASE NO.:
)	
Plaintiff,)	
)	
vs.)	
)	
C.R. BARD, INC. a New Jersey corporation,)	
and BARD PERIPHERAL VASCULAR, INC.,)	
an Arizona corporation,)	
)	
Defendants.)	JURY TRIAL DEMANDED

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

Plaintiff, VICKI WETZEL, by and through her undersigned attorneys, hereby sues Defendants C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC. (collectively hereinafter “Defendants”) and alleges as follows:

PARTIES

1. Plaintiff Vicki Wetzel, at all times relevant to this action, is and was a citizen of the state of Pennsylvania, and has resided, and continues to reside, in Glen Park, Pennsylvania.
2. On or about December 27, 2006, Plaintiff underwent placement of a Bard G2 IVC Filter at York Hospital, located in York, Pennsylvania.
3. On or about July 28, 2012, it was discovered that the G2 IVC Filter had fractured into pieces, and had tilted in a direction not consistent with initial implantation, causing injury and damage to Plaintiff. As a result, Plaintiff was forced to submit to extensive medical treatment and care, including but not limited to technically difficult surgery to attempt to remove

the IVC filter fragments. Despite removal of some fragments, a partially fractured arm of the filter still remains in Plaintiff's thorax.

4. Plaintiff has suffered, and will continue to suffer, significant damages including significant medical expenses, pain and suffering, loss of enjoyment of life, disability, and other losses. Plaintiff will require ongoing care to monitor the G2 IVC Filter to ensure that it does not cause additional or further injury.

5. Defendant C.R. BARD, INC. (hereinafter "BARD") is a corporation duly organized and existing under the laws of the state of New Jersey and has its principal place of business at 730 Central Avenue Murray Hill, New Jersey.

6. BARD, at all times relevant hereto, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the G2 Filter System to be implanted in patients across the United States, including Pennsylvania.

7. Defendant BARD PERIPHERAL VASCULAR, INC. (hereinafter "BPV"), is a wholly owned subsidiary corporation of BARD, and is a corporation duly organized and existing under the laws of the State of Arizona, with its principal place of business at 1625 West 3rd Street, Tempe, Arizona.

8. BPV, at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the G2 Filter System to be implanted in patients throughout the United States, including Pennsylvania.

JURISDICTION AND VENUE

9. Plaintiff has suffered damages in an amount that exceeds the jurisdictional amount of this Court, 28 U.S.C. Sec. 1332. Furthermore, as alleged in paragraphs 1, and 5 through 8 herein, the citizenship of the parties to this action is diverse.

10. Venue is proper in this Court, as the facts and circumstances leading to Plaintiff's injuries, occurred in York, Pennsylvania, and the G2 Filter System that is the subject of this action, was sold, purchased, and implanted into the Plaintiff's body in York, Pennsylvania. Furthermore, Defendants were authorized to conduct business in the State of Pennsylvania, and did conduct business in York, Pennsylvania.

GENERAL FACTUAL ALLEGATIONS

A. The G2 FILTER: KNOWN RISKS

11. Plaintiff brings this action as a result of serious personal injuries Plaintiff has suffered as a result of a surgically implanted medical device, known as a G2 Filter System (hereinafter "G2 Filter), failing and migrating within Plaintiff's body and causing serious and ongoing physical, emotional, and economic damages.

12. The G2 Filter was designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold by Defendants, in Pennsylvania, to prevent blood clots (thrombi) from traveling to the lower portions of the body to the heart and lungs.

13. Prior to Plaintiff being implanted with a G2 Filter in December 2006, Defendants knew and should have known that the device was defective and unreasonably dangerous for, *inter alia*, the following reasons:

a. Defendants failed to conduct appropriate clinical testing, such as animal studies, to determine how the device would function once permanently implanted in the human body.

b. Defendants knew and/or should have known that the G2 Filter had a high rate of fracture, migration, and excessive tilting and perforation of the vena cava wall once implanted into the human body. Defendants knew and/or should have known, that such failures exposed patients to serious injuries including, but not limited to: death, hemorrhage, cardiac/pericardial tamponade, cardiac arrhythmia and other symptoms similar to myocardial infarction, severe and persistent pain, perforations of tissue, vessels and organs, and the inability to remove the device.

c. Upon information and belief, Defendants also knew and/or should have known, that the certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device.

d. Defendants knew and/or should have known, that these risks for the G2 Filter were, and are, substantially higher than other similar devices.

e. Defendants knew and/or should have known that the G2 Filter was used to treat conditions of the type which Plaintiff suffered from.

f. Despite being aware of the aforementioned risks, Defendants marketed the device as one that reduced the aforementioned risks and was therefore, safe for use. Additionally, Defendants misrepresented, omitted, and/or failed to provide adequate warnings or instructions for use regarding said risks. Defendants also failed to issue a recall or to notify customers that a safer device was available.

B. INFERIOR VENA CAVA FILTERS: GENERALLY

14. Inferior vena cava (“IVC”) filters were initially marketed in the 1960s. Since that time, several medical device manufacturers have introduced several different designs of the filter into the market.

15. An IVC filter is a device that is designed to filter, or “catch” blood clots, or thrombi, that travel from lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either permanently or temporarily, in the human body, more specifically, within the inferior vena cava.

16. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, thrombi travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Often times, these thrombi develop in the deep leg veins. These thrombi are called “deep vein thrombosis” or “DVT.” Once thrombi reach the lungs, they are considered “pulmonary emboli” or “PE.” Pulmonary emboli present significant risks to human health. They can, and often do, result in death.

17. Certain people are at an increased risk for the development of DVT or PE. For instance, an individual who undergoes knee or hip joint replacement surgery is at risk for developing DVT/PE. Obese patients are also at increased risk for DVT/PE. So too are people who have vascular diseases or who have experienced previous strokes. A number of other conditions predispose people to develop DVT/PE, including “coagulopathies” and clotting disorders.

18. People at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox, to regulate the clotting factor of the blood. In some cases, however, physicians recommend implantation of an IVC filter to prevent thromboembolic events. Such cases include those of persons who are high risk for DVT/PE, or who cannot manage their conditions with medications.

19. In sum, IVC filters have been on the market for decades. The first filters were marketed as permanent filters, designed to be left in the patient’s inferior vena cava on a

permanent basis. Such devices have long-term follow-up data (of up to 20 years and longer) supporting their use and efficacy. Beginning in 2003, manufacturers also began marketing what are known as optional or retrievable filters. These filters are designed so that they can be surgically removed from a patient after the risk of PE has subsided. These IVC filter designs, however, were not intended to remain within the human body for indeterminate periods of time. In other words, the initial designs of retrievable IVC filters were intended to remain implanted for a finite period of time. The Recovery Filter System and the subsequent G2 Filter manufactured by BARD and BPV, however, are examples of non-permanent filters, designed to be retrievable in nature.

C. THE RECOVERY FILTER

i. FDA Clearance and Intended Use

20. In 2002, BARD and BPV submitted a notification of intent to the FDA to market the “RECOVERY Filter System” (hereinafter “RECOVERY Filter”) for the prevention of recurrent pulmonary embolism by placement in the inferior vena cava.¹

21. On November 27, 2002, the FDA cleared the RECOVERY® Filter for marketing and use in the prevention of recurrent pulmonary embolism via *permanent* placement in the vena cava in the following situations: (a) pulmonary thromboembolism when anticoagulants are contraindicated; (b) failure of anticoagulant therapy for thromboembolic disease; (c) emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and (d) chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

¹ BARD and BVP submitted the notification under Section 510(k) of the United States Food, Drug and Cosmetic Act (“Act”) of 1976 (21 U.S.C. 321 *et seq.*). The 510(k) review process requires any entity engaged in the design, manufacture, distribution, or marketing of a device intended for human use to notify the FDA 90 days before it intends to market the device, and to establish that the device is substantially equivalent to a legally marketed predicate device. (21 C.F.R. 807.81, 807.92(a)(3)). Substantial equivalence means that the new device has the same intended use and technological characteristics as the predicate device. This approval process allows a manufacturer to bypass the rigorous safety scrutiny required by the pre-market approval process.

22. In April 2003, Bard and BPV submitted a Section 510(k) premarket notification of intent to market the RECOVERY® Filter for the additional intended use of *optional retrieval*. The FDA cleared this additional intended use on July 25, 2003.

23. Bard and BPV began actually marketing the device in April 2003, but did not begin full market release until 2004. Bard and BPV were aware that the RECOVERY® filter was also used extensively off-label, including for purely prophylactic reasons for trauma patients or patients with upcoming surgeries such as bariatric procedures.

ii. What Is It and How Is It Used

23. The RECOVERY® Filter consists of two (2) levels of six (6) radially distributed NITINOL struts that are designed to anchor the filter into the inferior vena cava, and to catch any embolizing clots. There are six short struts, which are commonly referred to as the arms, and six long struts, which are commonly referred to as the legs. Each strut is held together by a single connection to a cap located at the top of the device. According to the Patent filed for this device, the short struts are primarily for “centering” or “positioning” within the vena cava, and the long struts with attached hooks are designed to primarily prevent the device from migrating in response to “normal respiratory movement” or “pulmonary embolism.”

24. As noted above, the RECOVERY® Filter is constructed with NITINOL, which is an acronym that stands for Nickel Titanium Naval Ordnance Laboratory. NITINOL possesses “shape memory.” That is, NITINOL will change shape according to changes in temperature, and then, retake its prior shape after returning to its initial temperature. When placed in saline, therefore, the NITINOL struts become soft and can be straightened to allow delivery through a small diameter catheter. The metal struts then reassume their original shape when warmed to body temperature in the vena cava.

25. The RECOVERY® filter is inserted by a catheter that is guided by a physician through a blood vessel into the inferior vena cava. The RECOVERY® Filter is designed to be retrieved in a similar fashion.

iii. Inherent Risks of the RECOVERY® Filter

26. The RECOVERY® Filter is prone to an unreasonably high risk of failure and patient injury following placement in the human body. Multiple studies have reported Bard's RECOVERY® Filter to have a fracture and migration rate ranging from 21% to 31.7%. When such failures occur, shards of the device, or the entire device, can travel to the heart, where it can cause cardiac tamponade, perforation of the atrial wall, myocardial infarction and death. These fractured shards may also become too embedded in tissue or migrate to other organ systems and vasculature, such as the renal veins, heart and lungs, such that they are too dangerous to remove. These patients are exposed to a lifetime of future risk.

27. The RECOVERY® Filter similarly poses a high risk of tilting and penetrating and perforating the vena cava walls. When such failures occur, the device can perforate the duodenum, small bowel, and ureter, which may lead to retroperitoneal hematomas, small-bowel obstructions, and extended periods of severe pain, and/or death. Further, given the risks of injury in attempting to remove devices that have penetrated or perforated the vena cava, the device may be irremovable. These patients are faced with a lifetime of future risk.

28. The RECOVERY Filter failures described above occur at a substantially higher rate than with other IVC filters.

29. The adverse event reports (AERs) associated with IVC filter devices demonstrates that Bard's IVC Filters to include the RECOVERY Filter are far more prone to device failure than are other similar devices.

30. These failures are attributable, in part, to the fact that the RECOVERY® Filter was designed so as to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

31. In addition to design defects, the RECOVERY® Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the device while *in vivo*. In particular, the RECOVERY

Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the RECOVERY Filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to failure.

iv. What Bard and BPV Knew or Should Have Known

32. Bard and BPV knew that no clinical testing, such as animal studies, was conducted to determine whether the RECOVERY® Filter would perform safely once implanted in the human body and subjected to normal *in vivo* stresses.

33. Soon after the G2® Filter's introduction to the market in 2003, Bard and BPV began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the RECOVERY® Filter was fracturing or migrating post-implantation and that fractured pieces and/or the entire device were migrating throughout the human body, including to other vessels, the heart and lungs. Bard and BPV also received large numbers of AERs reporting that the RECOVERY® Filter was found to have excessively tilted, migrated and/or perforated the inferior vena cava post-implantation. These failures were often associated with reports of severe patient injuries such as:

- a. death;
- b. hemorrhage;
- c. cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);
- d. cardiac arrhythmia and other symptoms similar to myocardial infarction;
- e. severe and persistent pain;
- f. and perforations of tissue, vessels and organs.

34. Bard and BPV received AERs reporting that the RECOVERY® Filter had

fractured *in vivo* and that the entire device had migrated *in vivo* some of which were reported to have been associated with patient death.

35. From 2003 through September 2005, Bard and BPV received ever growing numbers of AERs reporting the above described failures and patient injuries. Defendants knew or should have known that the failure rates associated with the RECOVERY® Filter were substantially higher than other similar products on the market.

v. *Market Withdrawal, but no Recall*

36. In late 2004 or early 2005 Bard and BPV, without notifying consumers of the design and manufacturing flaws inherent in the Recovery® Filter, began redesigning the Recovery® Filter in an attempt to correct those flaws. The redesigned filter is known as the G2® Filter, which stands for second generation Recovery® Filter. Once Bard and BPV had obtained FDA clearance to market the redesigned product in or around August 2005, Bard and BPV quietly stopped marketing the Recovery® Filter. Bard and BPV failed, however, to make any effort to notify consumers of the risk inherent in the use of the Recovery® Filter.

D. THE G2 FILTER SYSTEM

37. On August 10, 2005, Bard and BPV submitted a Section 510(k) premarket notification of intent to market the G2® Filter for the prevention of recurrent pulmonary embolism via placement in the inferior vena cava. Bard and BPV cited the Recovery® Filter as the substantially equivalent predicate device. Bard and BPV stated that the differences between the Recovery® Filter and the G2® Filter were primarily dimensional and no material changes or additional components were added. On August 29, 2005, the FDA cleared the Recovery® Filter for the same intended uses as the Recovery® Filter, except that it was not cleared for retrievable use.²

38. Bard and BPV marketed the G2® Filter as having “enhanced fracture resistance,” “improved centering,” and “increased migration resistance.” However, Bard and BPV again

² The FDA did not clear the G2® Filter to be used as a retrievable filter until January 15, 2008.

failed to conduct adequate clinical testing, such as animal studies, to ensure that the device would perform safely and effectively once implanted in the human body and subjected *in vivo* stresses. Not surprisingly, the G2® Filter's design causes it to be of insufficient integrity and strength to withstand normal *in vivo* body stresses within the human body so as to resist fracturing, migrating, tilting, and/or perforating the inferior vena cava.

39. Also, like its predecessor, in addition to design defects, the G2® Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of “draw markings” and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the G2® Filter while *in vivo*. In particular, the G2® Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the G2® Filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to fatigue failure and migration.

40. Thus, the G2® Filter shares similar defects and health risks as its predicate device.

41. As with the Recovery® Filter, Bard and BPV immediately began receiving large numbers of AERs reporting that the G2® Filter was, *inter alia*, fracturing, migrating, excessively tilting, and perforating the vena cava once implanted. These failures were again often associated with reports of severe patient injuries such as:

- a. death;
- b. hemorrhage;
- c. cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);
- d. cardiac arrhythmia and other symptoms similar to myocardial infarction;
- e. severe and persistent pain;

f. and perforations of tissue, vessels and organs.

42. Defendants represent the fracture rate of the G2® Filter to be 1.2%. Based upon a review of the data available in the public domain (including the FDA MAUDE database statistics and the published medical literature), this representation does not accurately reflect the true incidence of device fracture for the G2® Filter.

43. A review of the MAUDE database from the years 2004-2008 reveals data to establish that the Bard and BPV's vena cava filters (including the G2® Filter) are responsible for the majority of all reported adverse events related to inferior vena cava filters.

E. BARD AND BPV'S KNOWLEDGE OF THE RISK OF FAILURE AND RESULTING DANGERS

44. Upon information and belief, Plaintiff alleges that as early as 2003, Bard and BPV were aware of, and/or had knowledge of, and/or should have had knowledge of the fact that the Recovery® Filter was defective, and unreasonably dangerous, and was causing injury, and death, to patients who had received it. Similarly, Bard and BPV were aware, as early as 2005 that the G2® Filter System was defective, and unreasonably dangerous, and was causing injury, and death, to patients who received it.

45. Data establishes that the failure rates of the Recovery® Filter and G2® Filter are/were exceedingly higher than the rate that Bard and BPV have in the past, and currently continue to publish to the medical community, members of the public. Further, Bard and BPV were aware, and/or or should have been aware that the Recovery® Filter and G2® Filter have substantially higher failure rates than do other similar products on the market, yet Defendants failed to warn consumers of this fact.

46. Upon information and belief, from the time the G2® Filter System became available on the market, the Defendants Bard and BPV embarked on an aggressive campaign of "off label marketing" concerning the G2® Filter System. This included representations made to physicians, healthcare professionals, and other members of the medical community that the G2®

Filter System was safe and effective for retrievable use prior to the FDA approving the G2® Filter System for retrievable use.

47. The conduct of Bard and BPV, as alleged in this Complaint, constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff. Bard and BPV had actual knowledge of the dangers presented by the Recovery Filter® and G2® Filter, yet consciously failed to act reasonably to:

- a. Inform or warn Plaintiff, Plaintiff's physicians, or the public at large of these dangers;
- b. Establish and maintain an adequate quality and post-market surveillance system; and
- c. Recall the Recovery® Filter and G2® Filter from the market.

48. Despite having knowledge as early as 2003 of the unreasonably dangerous and defective nature of the Recovery® Filter, Bard and BPV consciously disregarded the known risks and continued to actively market and offer for sale the Recovery® and, subsequently, the G2® Filter Systems.

49. Plaintiff further alleges that the Defendants acted in willful, wanton, gross and total disregard for the health and safety of the users or consumers of their Recovery® Filter and G2® Filter Systems, acted to serve their own interests, and having reason to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

SPECIFIC FACTUAL ALLEGATIONS REGARDING PLAINTIFF

50. On December 27, 2006, Plaintiff underwent surgical placement of a G2 Filter at York Hospital, York, Pennsylvania.

51. This G2® Filter device was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants Bard and BPV.

52. The G2® Filter subsequently fractured into pieces and tilted in a position inconsistent with initial implantation.

53. Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, loss of enjoyment of life, disability, and other losses. Plaintiff will require ongoing medical care to monitor the G2 Filter and the Plaintiffs surrounding anatomy.

FRAUDULENT CONCEALMENT

54. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by Defendants when they had a duty to disclose those facts. They have kept Plaintiff ignorant of vital information essential to the pursuit of their claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's part in filing on their causes of action. Defendants' fraudulent concealment did result in such delay.

55. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the Recovery® and G2® Filter Systems.

56. Plaintiff and Plaintiff's health care providers could not reasonably have discovered the claims made herein, until at the earliest the device was discovered to have migrated to Plaintiff's renal vein, at which time she learned of her health care providers' inability to remove the filter.

57. The Defendants are and were under a continuing duty to disclose the true character, quality, and nature of the device, that was implanted in Plaintiff, but instead they concealed them. Defendants' conduct, as described in this complaint, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

CORPORATE/VICARIOUS LIABILITY

58. At all times herein mentioned, each of the Defendants was the agent, servant, partner, co-conspirator and/or joint venturer of each of the other Defendants herein, and was, at all times, operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and

encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

59. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

60. At all times herein mentioned, Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by the Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.

61. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

FIRST CAUSE OF ACTION
NEGLIGENCE

62. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 61 as though fully set forth herein.

63. At all times relevant to this cause of action, the Defendants Bard, BPV, were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the Recovery® and G2® Filters.

64. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the G2® Filter that was implanted in Plaintiff.

65. Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the G2® Filter so as to avoid exposing others to foreseeable and unreasonable risks of harm.

66. Defendants knew or reasonably should have known that the G2® Filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

67. At the time of manufacture and sale of the G2 Filter, Defendants knew or should have known that the G2® Filter:

- a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;
- b. Was designed and manufactured so as to present a unreasonable risk of migration of the device and/or portions of the device;
- c. Was designed and manufactured so as to present a unreasonable risk of the device tilting and/or perforating the vena cava wall; and/or
- d. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

68. At the time of manufacture and sale of the G2 Filter, Defendants knew and/or should have known that using the G2® Filter in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by

the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

69. Defendants knew or reasonably should have known that consumers of the G2® Filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

70. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the G2® Filter in, among other ways, the following acts and omissions:

- a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;
- b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other device available for the same purpose;
- c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;
- d. Failing to use reasonable care to warn or instruct, including pre and post sale, Plaintiff, Plaintiff's physicians, or the general health care community about the Recovery® Filter's substantially dangerous condition or about facts making the product likely to be dangerous;
- e. Failing to perform reasonable pre and post-market testing of the Recovery® Filter to determine whether or not the product was safe for its intended use;
- f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre and post sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Recovery® Filter;
- g. Advertising, marketing and recommending the use of the Recovery® Filter, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of the Recovery® Filter;
- h. Representing that the Recovery® Filter was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

- i. Continuing manufacture and sale of the Recovery® Filter with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with FDA good manufacturing regulations;
- j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Recovery® Filter so as to avoid the risk of serious harm associated with the use of the Recovery® Filter;
- k. Advertising, marketing, promoting and selling Recovery® Filter for uses other than as approved and indicated in the product's label;
- l. Failing to establish an adequate quality assurance program used in the manufacturing of the Recovery® Filter; and
- m. Failing to establish and maintain an adequate post-market surveillance program.

71. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

72. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiff makes demand for judgment against Defendants, and requests compensatory damages for pain and suffering, payment for the medical costs and expenses incurred, punitive and exemplary damages, prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees as allowed by law, and any and all other relief the Court deems just and proper; and further, demand a trial by jury of all issues.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY - FAILURE TO WARN

73. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 61 as though fully set forth herein.

74. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the G2® Filter, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

75. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, Defendants knew or should have known the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use. Specifically, Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the G2® Filter, which was implanted in Plaintiff, that the G2® Filter, *inter alia*, posed a significant and higher risk than other similar devices of device failure (fracture, migration, tilting, and perforation of the vena cava wall) and resulting serious injuries. Upon information and belief, Defendants also knew or should have known that certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device.

76. Therefore, Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device. Defendants further had a duty to warn of dangers and proper safety instructions that it became aware of even after the device was distributed and implanted in Plaintiff.

77. Despite this duty, Defendants failed to adequately warn of material facts regarding the safety and efficacy of the G2® Filter, and further failed to adequately provide instructions on the safe and proper use of the device.

78. No health care provider, including Plaintiff's, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the device.

79. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

80. Plaintiff and Plaintiff's health care providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

81. Therefore, the G2® Filter implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

82. The G2® Filter implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

83. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiff makes demand for judgment against Defendants, and requests compensatory damages for pain and suffering, payment for the medical costs and expenses incurred, punitive and exemplary damages, prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees as allowed by law, and any and all other relief the Court deems just and proper; and further, demand a trial by jury of all issues.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

84. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 61 as though fully set forth herein.

85. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the G2® Filter, including the one implanted in Plaintiff.

86. The G2® Filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Defendants' possession. In the alternative, any changes that were made to Recovery® Filter implanted in Plaintiff were reasonably foreseeable to Defendants.

87. The G2® Filter implanted in Plaintiff was defective in design because it failed to perform in a manner reasonably expected by consumers given its nature and intended function.

88. The G2® Filter implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits.

89. Plaintiff and Plaintiff's health care providers used the G2® Filter in a manner that was reasonably foreseeable to Defendants.

90. Neither Plaintiff, nor Plaintiff's health care providers could have by the exercise of reasonable care discovered the device's defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the device.

91. As a direct and proximate result of the G2® Filter's defective design, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiff makes demand for judgment against Defendants, and requests compensatory damages for pain and suffering, payment for the medical costs and expenses incurred, punitive and exemplary damages, prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees as allowed by law, and any and all other relief the Court deems just and proper; and further, demand a trial by jury of all issues.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

92. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 59 as though fully set forth herein.

93. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the G2® Filter that was implanted into Plaintiff.

94. The G2® Filter implanted in Plaintiff contained a condition, which Defendants did not intend, at the time it left Defendants' control and possession.

95. Plaintiff and Plaintiff's health care providers used the device in a manner that was reasonably foreseeable to Defendants.

96. As a result of this condition, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

97. As a direct and proximate result of the G2® Filter's manufacturing defect, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiff makes demand for judgment against Defendants, and requests compensatory damages for pain and suffering, payment for the medical costs and expenses incurred, punitive and exemplary damages, prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees as allowed by law, and any and all other relief the Court deems just and proper; and further, demand a trial by jury of all issues.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

98. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 59 as though fully set forth herein.

99. At all times relevant to this action, Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the G2® Filter for use as a surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

100. At the time and place of the sale, distribution, and supply of the Defendants' G2® Filter System to Plaintiff by way of Plaintiff's health care providers and medical facilities, Defendants expressly represented and warranted, by labeling materials submitted with the product, that the G2® Filter System was safe and effective for its intended and reasonably foreseeable use.

101. Defendants knew of the intended and reasonably foreseeable use of the G2® Filter, at the time they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product to be of merchantable quality, and safe and fit for its intended use.

102. Defendants impliedly represented and warranted to the healthcare community, Plaintiff and Plaintiff's health care providers, that the G2® Filter was safe and of merchantable

quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

103. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the G2® Filter was defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used in its intended and/or reasonably foreseeable manner. Specifically, at the time of Plaintiff's purchase of the G2® Filter from the Defendants, through Plaintiff's physicians and medical facilities, it was not in a merchantable condition in that:

- a. It was designed in such a manner so as to be prone to a statistically high incidence of failure, including fracture, migration, excessive tilting, and perforation of the inferior vena cava;
- b. It was designed in such a manner so as to result in a statistically significant incidence of injury to the organs and anatomy; and
- c. It was manufactured in such a manner so that the exterior surface of the Recovery® Filter System was inadequately, improperly and inappropriately prepared and/or finished causing the device to weaken and fail.

104. Plaintiff and Plaintiff's health care providers reasonably relied on the superior skill and judgment of Defendants as the designers, researchers and manufacturers of the product, as to whether G2® Filter was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the G2® Filter was manufactured and sold.

105. Defendants placed the G2® Filter into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which the G2® Filter was manufactured and sold.

106. Defendants breached their implied warranty because their G2® Filter was not fit for its intended use and purpose.

107. As a proximate result of Defendants breaching their implied warranties, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiff makes demand for judgment against Defendants, and requests compensatory damages for pain and suffering, payment for the medical costs and expenses incurred, punitive and exemplary damages, prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees as allowed by law, and any and all other relief the Court deems just and proper; and further, demand a trial by jury of all issues.

SIXTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

108. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 59 as though fully set forth herein.

109. At all times relevant to this cause, and as detailed *supra*, Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information concerning the G2® Filter, including, but not limited to, misrepresentations relating to the following subject areas:

- a. The safety of the G2® Filter;
- b. The efficacy of the G2® Filter;
- c. The rate of failure of the G2® Filter; and
- d. The approved uses of the G2® Filter.

110. The information distributed by Defendants to the public, the medical community and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the G2® Filter. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These

materials included instructions for use and warning document that was included in the package of the G2® Filter that was implanted in Plaintiff.

111. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the G2® Filter and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the G2® Filter.

112. The foregoing representations and omissions by Defendants were in fact false. The G2® Filter is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the G2® Filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered. Further, the device has a significantly higher rate of failure and injury than do other comparable devices.

113. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did use the G2® Filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.

114. Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if the true facts regarding the device had not been concealed and misrepresented by Defendants.

115. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the G2® Filter.

116. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the G2® Filter, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

117. Plaintiff, Plaintiff's health care providers and general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the G2® Filter.

118. Plaintiff and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Defendants' was the direct and proximate cause of Plaintiff's injuries as described herein.

WHEREFORE, Plaintiff makes demand for judgment against Defendants, and requests compensatory damages for pain and suffering, payment for the medical costs and expenses incurred, punitive and exemplary damages, prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees as allowed by law, and any and all other relief the Court deems just and proper; and further, demand a trial by jury of all issues.

SEVENTH CAUSE OF ACTION
PUNITIVE DAMAGES

119. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

120. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare.

121. Defendants had knowledge of, and were in possession of evidence demonstrating that, the Recovery® Filter was defective and unreasonably dangerous and had a substantially higher failure rate than did other similar devices on the market. Yet, Defendants failed to:

- a. Inform or warn Plaintiff or her health care providers of the dangers;
- b. To establish and maintain an adequate quality and post-market surveillance system; and

c. Recall the G2® Filter from the market

122. Defendants acted to serve their own interests and having reasons to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

123. As a direct, proximate, and legal result of Defendants' acts and omissions a described herein, and Plaintiff implantation with Defendants' defective product, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

WHEREFORE, Plaintiff makes demand for judgment against Defendants, and requests compensatory damages for pain and suffering, payment for the medical costs and expenses incurred, punitive and exemplary damages, prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees as allowed by law, and any and all other relief the Court deems just and proper; and further, demand a trial by jury of all issues.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendants as follows:

- (a) For general damages in a sum in excess of the jurisdictional minimum of this Court;
- (b) For medical, incidental, and hospital expenses according to proof;
- (c) For pre-judgment and post-judgment interest as provided by law;
- (d) For compensatory damages in excess of the jurisdictional minimum of this Court;
- (e) For consequential damages in excess of the jurisdictional minimum of this Court;
- (f) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendant the seriousness of its conduct and to deter similar conduct in the future relative to its total wealth;

- (g) For attorneys' fees, expenses, and costs of this action; and
- (h) For all further relief this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: 5/7/14

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